MAY 1 3 2011

510(k) Summary

mahemedical

K102845

>> 510(k) Summary as required by section 807.92(c)

Submission Applicant:
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Date: 5/11/2011

Application Correspondent/Contact:
think!
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Germany
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**Common name:** Implant Plates/ Screws, Bone Plates/Screws, Bone Fixation System

**Classification name:**
> 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories.

**Product Codes**: HRS – Plate, Fixation, Bone
HWC – Screw, Fixation, Bone

> 21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener

**Product Code**: HTY – Pin, Fixation, Smooth

**Trade name:** Mahe Fixation Plate and Screw System

**Predicate Devices:**
> K083654 & K082527 - *Zimmer*® Universal Locking System: 2.7 mm and 3.5 mm Locking Plates and Screws *(Tivanium*® Ti-6A1-4V Alloy, CP Grade Titanium) - Zimmer, Inc.
> K091614 - OsteoMed Foot Plate and Screw Rigid Fixation System - OsteoMed L. P.
> K083912 - Treu Bone Fixation Screws and Pins – Treu Instrumente GmbH

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**Description of the Device:**

Mahe Fixation Plate and Screw System consists of various shape and sizes plates featuring compression and locking or non-locking holes, fullthreaded-cortical, short threaded-cancellous, locking or non-locking, cannulated, self-tapping or non-self-tapping screws, compression and dynamic screws, implantable K-wires, pins, washers, and appropriate instrumentation. Surgical instrumentation is provided to facilitate modification, insertion, and removal of implants.

The plates and screws are fabricated from stainless steel and titanium.

The system contains several modules based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle, or other bones appropriate for the size of the device. The plate implants are in following models available: Tubular Plates, Reconstruction Plates, Cloverleaf Plates, T-Plates, Calcaneus Plates, Anatomical Plates, Clavicula Hook Plates, Small Fragment, Locking Plates, and DHSP/DCSP Screw Plates. The thickness of the plates varies from 1.2mm to 10mm; the length varies from 26mm to 317mm; and the number of the holes varies from 2 to 22. The screw implants are in three different diameter sizes (2.7mm, 3.5mm, and 4.0mm) and the K-wire implants are in various lengths (from 70mm to 310mm) and diameter sizes (from 0.8 to 3mm) available.

The system is sold non-sterile, the products have to be sterilized prior to use.

**Indications for Use:**

The Mahe Fixation Plate and Screw System is indicated for fracture fixation and joint fusion in the pelvis, small bones and long bones. Examples include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, clavicle, humerus, ulna, middle hand and middle foot bones; and treatment of the calcaneus. The system is indicated for use in adult patients. All implants are intended for single use only.

**Technological characteristics compared to the Predicate Devices:**

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use, design, sizes and configurations. In addition, the classifications, manufacturing and sterilization methods of the predicate and subject components are identical. The Mahe Fixation Plate and Screw System and predicate devices are made from Titanium (alloy) and Stainless Steel. Functional and mechanical testing demonstrates the comparable mechanical properties of the Mahe Fixation Plate and Screw System to the predicate devices K083654 & K082527 *Zimmer*® Universal Locking System, K091614 OsteoMed Foot Plate and Screw Rigid Fixation System and K083912 Treu Bone Fixation Screws and Pins.

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The Mahe Fixation Plate and Screw System can be deemed substantially equivalent and safe and effective for its indicated use.

**Non-clinical performance data:**

Mahe certifies compliance with the requirements among others of following device relevant standards: ISO 5838 "Implants for surgery - Skeletal pins and wires", ASTM F366-04 "Standard Specification for Fixation Pins and Wires", ASTM F0543-07 "Standard Specification and Test Methods for Metallic Medical Bone Screws" and ASTM F 382-99 "Standard Specification and Test Method for Metallic Bone Plates". Moreover biocompatibility and mechanical tests have been performed on the Mahe Fixation Plate and Screw System.

**Summary:**

The presented data that was conducted on the Mahe Fixation Plate and Screw System shows in its results and in comparison that the products perform as well as or better than the predicate devices, safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched and do not raise new questions regarding safety and effectiveness of the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Mahe Medical GmbH
% Ms. Andrea Pecsi
Schwarzwaldstraße 5
78532 Tuttlingen
Germany

MAY 13 2011

Re: K102845
Trade/Device Name: Mahe Fixation Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTY
Dated: April 8, 2011
Received: April 15, 2011

Dear Ms. Pecsi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

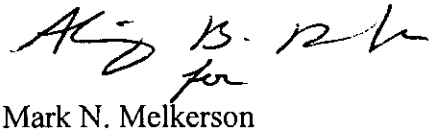
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102845 (1/1)

## Indications for Use Statement

510(k) Number (if known): K102845

Device Name:
**Mahe Fixation Plate and Screw System**

Indications for Use:

The Mahe Fixation Plate and Screw System is indicated for fracture fixation and joint fusion in the pelvis, small bones and long bones. Examples include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, clavicle, humerus, ulna, middle hand and middle foot bones; and treatment of the calcaneus. The system is indicated for use in adult patients. All implants are intended for single use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102845